

ORSETT BRIEFING PAPERS FOR PSYCHOLOGISTS

No.3 - Clinical Trials

Introduction

Any therapy or treatment needs to be assessed for its effectiveness or efficacy. The way to do this experimentally is to compare a group receiving the treatment or therapy with a group that does not. It would be expected that the former group shows a greater improvement over a set period of time.

A clinical trial can be defined as "a carefully and ethically designed experiment with the aim of answering some precisely framed question" ¹.

However, there are a number of quasi-experimental variations of the clinical trial.

For a clinical trial to be carefully and ethical designed, there are a number of general problems to address. Particularly when aiming to design the "randomly controlled trial" (RCT), which is seen as the best type of clinical trial.

The general problems with clinical trials are:

i) The appropriate measurement of baseline and improvement. It is necessary to use a measure that can be compared before and after the trial. In most cases today, self-reported questionnaires or psychometric tests are used.

ii) To control for equality in symptoms among the conditions. Strict inclusion and exclusion criteria are used to try to equalise the level of the disorder among the different conditions.

¹ Hill, A.B (1955) Introduction to Medical Statistics (5th ed) London: Lancet.

iii) To overcome the knowledge of who is in the control or placebo group by the researchers or the participants. This problem is addressed by the use of "blinding". In an "open" trial, both researchers and participants know which group they belong to.

With "blind-at-randomisation", participants are divided into the conditions with no prior knowledge of the condition, but they may soon learn as the trial develops. For example, the presence of side effects with the drug condition, and not with the placebo condition.

"Single-blind" design is where the participants cannot tell which condition, but the researchers know. But, best of all, is "double-blind" design, where neither the researcher nor the participants know which condition is which.

iv) The ethics of denying treatment in the control or placebo group. One traditional method used here is to make the control group those on a waiting list for treatment. Alternatively, gain informed consent for the participants: making them fully aware that they may be in the placebo or control group when randomised.

Attempts have been made to have the "no treatment" group as similar as the treatment group when comparing therapies. The therapist attempts to direct the patient towards topics assumed to be irrelevant. Others have tried the client and therapist doing recreational activities for the allotted time of therapy ². However, these may still influence the client to improve. There are also ethical issues here.

v) Participants dropping out during the clinical trial. There are a number of reasons and points for drop-outs:

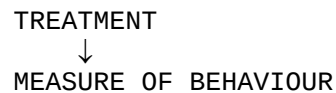
- At baseline stage before randomisation;
- Discovered later to have another disorder not being studied;
- Randomised to one group but given wrong treatment;
- Side effects of treatment leads to dose reduced or stopped;
- Leaves during trial or defaults on treatment.

To some degree, the problem of drop-out is hard to stop. The simplest answer is to start with a large number of participants.

² Edmonstone, M & Freeman, C (1992) Research in psychotherapy. In Freeman, C & Tyrer, P (eds) Research Methods in Psychiatry (2nd ed) London: Royal College of Psychiatrists.

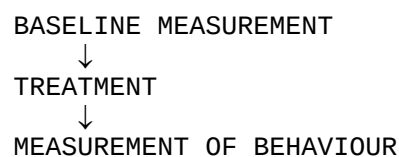
ONE GROUP POST-TEST DESIGN

This involves one group of participants assessed only after receiving the treatment or therapy. It is similar to the natural experiment. It is an opportunist design, but there is no baseline measurement.



ONE GROUP PRE-TEST/POST-TEST DESIGN (PRE-POST DESIGN)

One group of participants are receiving treatment or therapy, but they are assessed before and after the treatment. This is a quasi-experimental design. This design shows any improvement for those on treatment, but has no control group for comparison.



PRE-TEST/POST-TEST CONTROL GROUP (NO TREATMENT CONTROL)

Here participants are randomly allocated to treatment or no treatment groups. Measurement is made before and after the treatment or therapy. This is similar to an independent design experiment.

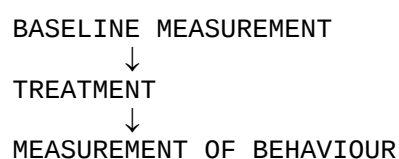
ADVANTAGES

- Allows comparison between treatment and no treatment
- Controls for spontaneous remission in no treatment group

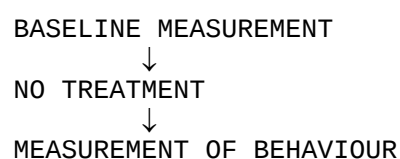
DISADVANTAGE

- Participants can guess which group and thus effects of expectation of improvement in treatment group

Treatment group



No treatment group



PRE-TEST/POST-TEST CONTROL GROUP (PLACEBO CONTROL)

Similar to pre-test/post-test control group above, but the "no treatment" group receives a placebo of the treatment or therapy. This is also similar to an independent design experiment.

ADVANTAGES

- Allows comparison between treatment and placebo

DISADVANTAGE

- Participants can guess if placebo or treatment group (eg: by presence or absence of side effects with drug treatments)

Treatment group

BASELINE MEASUREMENT



TREATMENT



MEASUREMENT OF BEHAVIOUR

Placebo group

BASELINE MEASUREMENT



PLACEBO



MEASUREMENT OF BEHAVIOUR

POST-TEST CONTROL GROUP

This type of clinical trial uses two groups involving treatment or no treatment/placebo, but measurement is only made after the treatment or therapy is completed. This is a quasi-experimental design.

ADVANTAGE

- Comparison of results after treatment

DISADVANTAGE

- No baseline measurement

Treatment group

TREATMENT



MEASUREMENT OF BEHAVIOUR

Control group

NO TREATMENT



MEASUREMENT OF BEHAVIOUR

CROSSOVER DESIGN

In this type of clinical trial, participants are randomly allocated to treatment or not treatment/placebo group for the first part of trial, then the groups changed over for the second part. This type can be called a "randomised controlled trial" (RCT). It is similar to a repeated measures experiment.

Where this design is used for drug trials, there has to be a "washout" period for the drug to leave the body. This is important to avoid confounding the conditions of the drug trial.

ADVANTAGE

- Controls for spontaneous remission and expectations of improvement

DISADVANTAGE

- Ethics of giving and removing treatment

Group 1

BASELINE MEASUREMENT
↓
TREATMENT
↓
MEASUREMENT OF BEHAVIOUR
↓
WASHOUT PERIOD
↓
PLACEBO
↓
MEASUREMENT OF BEHAVIOUR

Group 2

BASELINE MEASUREMENT
↓
PLACEBO
↓
MEASUREMENT OF BEHAVIOUR
↓
↓
↓
TREATMENT
↓
MEASUREMENT OF BEHAVIOUR

MULTICENTRE TRIALS (COMPARATIVE OUTCOME STUDY)

Here there are several groups of treatment and no treatment/placebo at different centres. For example, different hospitals or GPs caseloads, and different countries. This is an experimental design, and can be classed as a randomised controlled trial (RCT).

ADVANTAGES

- Control for participant characteristics at one particular centre
- Controls for spontaneous remission

DISADVANTAGE

- Problem of standardising procedures across many centres

Centre 1

Treatment group

BASELINE
MEASUREMENT



TREATMENT



MEASUREMENT
OF BEHAVIOUR

Control group

BASELINE
MEASUREMENT



NO TREATMENT



MEASUREMENT
OF BEHAVIOUR

Centre 2

Treatment group

BASELINE
MEASUREMENT



TREATMENT



MEASUREMENT
OF BEHAVIOUR

Control group

BASELINE
MEASUREMENT



NO TREATMENT



MEASUREMENT
OF BEHAVIOUR

SOURCES

Cohen, A & Posner, J (1995) A Guide to Clinical Drug Research
Dodrecht, Netherlands: Kluwer Academic Publishers

Freeman, C & Tyrer, P (1992) (eds) Research Methods in Psychiatry (2nd ed)
London: Royal College of Psychiatrists (Johnson, T: Statistical methods and clinical trials)

Lieberman, J.A et al (1999) Issues in clinical research design: Principles, practices and controversies. In Pincus, H.A, Lieberman, J.A & Ferris, S (eds) Ethics in Psychiatric Research Washington DC: American Psychiatric Association

Parry, G & Watts, F.N (1989) (eds) Behavioural and Mental Health Research: A Handbook of Skills and Methods Hove, Sussex: Lawrence Erlbaum

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An independent academic psychologist, based in England, who has written extensively on different areas of psychology with an emphasis on the critical stance towards traditional ideas.

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